DEC 2 0 2000

K003564

# 510(k) Summary
# for the HAKIM Programmer and Transmitter

**Codman & Shurtleff, Inc.**
**325 Paramount Drive**
**Raynham, MA 02767-0350**

**Contact Person**

Laura O'Grady
Sr. Regulatory Affairs Specialist
Telephone Number: (508) 828-3164
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**Name of Device**

Proprietary Name: HAKIM Programmer and Transmitter
Common Name: Hydrocephalus Valve Programmer
Classification Name: Central Nervous System Fluid Shunt and Components

**Device Classification**

This device has been placed in Class II for Central Nervous System Fluid Shunt and Components devices per 21 CFR § 882.5550 (84JXG).

**Statement of Substantial Equivalence**

The modified HAKIM Programmer and Transmitter is substantially equivalent to the original HAKIM Programmer and Transmitter, based on the subject device's similarity to the predicate devices in intended use, materials, design, and principles of operation.

**Indications for Use**

The HAKIM Programmer and Transmitter is indicated for use as an accessory to the HAKIM Programmable Valve Systems Product Line, to adjust the valve pressure setting as determined by the physician. The Hakim Programmer & Transmitter are designed for use only with Hakim Programmable Valves in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain.

**Physical Description**

The modified HAKIM Programmer and Transmitter consist of the Programmer module and the Transmitter. The Transmitter has an integral cord for connection to the Programmer module.

The Programmer is an electronic module that houses the power and control circuits. The Control Panel on the front of the programmer features a programming information display panel and a drawing of the programmable portion of the Codman HAKIM Programmable Valve (CHPV), as it appears when x-rayed. The buttons used to program the pressure setting of the valve and choose the language for the display are also on the Control Panel.

The Transmitter provides the programming signal to the CHPV. An integral cord connects the Transmitter to the Programmer. The Transmitter has a round 'head' with a central illuminated opening, and four 'legs' which are placed around the implanted CHPV on the scalp. The CHPV is located under the scalp through the illuminated opening in the Transmitter head, for programming.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2000

Ms. Laura O'Grady, RAC
Senior Regulatory Affairs Specialist
Codman & Shurtleff, Inc.
325 Paramount Drive
Raynham, Massachusetts

Re: K003564
Trade Name: HAKIM Programmer and Transmitter
Regulatory Class: II
Product Code: JXG
Dated: November 17, 2000
Received: November 20, 2000

Dear Ms. O'Grady :

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K003564

**Device Name** **HAKIM Programmer and Transmitter**

**Indications For Use:**

The HAKIM PROGRAMMER AND TRANSMITTER is designed for use only with CODMAN HAKIM Programmable Valves in the treatment of hydrocephalus when shunting cerebrospinal fluid (CSF) from the ventricles of the brain. It is used to program the HAKIM Programmable Valve to the selected pressure setting.

(Please do not write below this line - Continue on another page if necessary)
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 003564

Prescription Use X
(Per 21 CFR §801.109)

OR

Over-the-Counter Use_____

(Optional Format 1-2-96)